

maximum particle size of the granules is about 1,400 μm or less and in which the granulated sweetener exhibits a rate of dissolution in water which is greater than that exhibited by granules of Aspartame alone.

The inventors have surprisingly found that the presently claimed granulated sweeteners exhibit a higher dissolution rate as compared to either Aspartame alone or a mixture of Aspartame powder and Acesulfame-K powder.

The cited reference contains no disclosure or suggestion of such a granulated sweetener. Moreover, this reference contains no teaching which would suggest the improved solubility properties of the presently claimed granulated sweeteners. Accordingly, this reference cannot affect the patentability of the present claims.

The rejection of Claims 1-3, 5, 7, and 9-19 under 35 U.S.C. § 103(a) in view of Muhammad et al is respectfully traversed.

Muhammad et al disclose certain sweetener compositions which contain Aspartame and Acesulfame-K. However, the sweetener compositions of Muhammad et al differ from those of the present claims in a number of key ways. As stated in the responses filed on March 19, 2002 and September 19, 2002, the disclosure by Muhammad et al is deficient for the following reasons:

1) As conceded on page 2 paper number 23, Muhammad et al is silent in regard to the particle size of the disclosed product. Not only is Muhammad et al silent with respect to the particle size, in the present specification, the Applicants have found that when the particle size of the granulated sweetener is 1,400 μm or less the sweetener exhibits an *unexpectedly* improved dissolution rate (see, e.g., page 5, lines 4-10, of the specification);

2) The present claims are directed toward granulated sweeteners, while Muhammad et al is completed unconcerned with granulated sweeteners; and

3) The present claims are explicitly recite that the claimed sweeteners exhibit a dissolution rate which is greater than that exhibited by granules of Aspartame alone. In sharp contrast, Muhammad et al is concerned with the production of sweeteners which exhibit a delayed release (*see, e.g.*, the Abstract of Muhammad et al). Thus, the presently claimed sweetener compositions exhibit an improved rate of dissolution which could not have been expected from the teachings of Muhammad et al.

To support the distinctions between the present invention and Muhammad et al and to underscore these deficiencies in the disclosure of Muhammad et al, Applicants filed a Declaration under 37 C.F.R. § 1.132 of Yuichi Suzuki, one of the named inventors of this application ("March 19th Declaration"), on March 19, 2002 demonstrating that the rate of dissolution of a series of mixtures of granules of Aspartame and granules of Acesulfame-K (analogous to Muhammad et al) were inferior to the dissolution rate of a series of granules of mixtures of Aspartame and Acesulfame-K (as in the present invention). Moreover, Applicants point to the data presented in Tables 1 and 2 given on pages 11 and 12 of the specification, which show that the presently claimed sweetener compositions exhibit an improved rate of dissolution.

Despite this showing, the Examiner maintains that this showing is insufficient. The Examiner bases this position on the following points:

- a) lack of statistical analysis to support the conclusion;
- b) the results "do not seem to support unexpected results for the broad range that is claimed;" and

c) it is "not clear why the data for 90% ACE-K is combined and only some of the granules are "non-sieved."

With respect to point (c) made by the Examiner, Applicants submit that reason for why the data for 90% ACE-K is combined and only some of the granules are "non-sieved" is that the data for neither sieved granules of mixture nor sieved mixture of granules were collected at the 90% ACE-K level at the time of the March 19th Declaration. The reason for not collecting this data was because it was thought that the dissolution rate of ACE-K into water is overwhelmingly large as compared with that of APM as is shown in Table 1 of the instant specification (see page 11) and, accordingly, any sieved data is not required for as much as 90% ACE-K.

However, to alleviate any concerns that the Examiner may have, Applicants submit herewith a second Declaration under 37 C.F.R. § 1.132 by Mr. Yuichi Suzuki ("second Declaration"). In the second Declaration, Mr. Suzuki performed supplemental experiments with 90 % by weight ACE-K and 10 % by weight APM, the results of which have been added to Table 2, reproduced below for the Examiner's convenience:

Table 2: Time periods for dissolution (min)

Ratio of ACE-K present (% by weight)	5		20		50		90	
Particle size (μm)	Granules of mixture	Mixture of granules	Granules of mixture	Mixture of granules	Granules of mixture	Mixture of granules	Granules of mixture	Mixture of granules
500 to 1,400	27*	33*	24	31	13*	25*	4**	26**
300 to 500	8*	17*	11	17	4*	13*	2**	13**
100 to 300	6*	16*	4	18	3*	15*	2**	14**
to 100	27*	32*	5	27	4*	22*	3**	14**
non-sieved	26	32	-	-	14	27	4	24

** = Newly obtained data

* = Data presented in the March 19, 2002 Declaration under 37 C.F.R. §1.132

unmasked = Original Data presented in the specification in Table 2 appearing on page 12.

As is clearly evident from this data, for at as much as 90% ACE-K level unexpectedly shows that granules of mixture gave extremely shortened time periods for dissolution as compared with mixtures of granules, as was also shown at the other ratios provided in the March 19th Declaration.

With respect to point (b) made by the Examiner, it appears that the Examiner has misunderstood the data presented in the table above. As the Examiner notes, the present claims recite "about 1,400 μm or less;" however, the Examiner has focused on the relationship of between time required for dissolution of granules of mixture at 500 to 1,400 μm and at up to 100 μm . However, both of these ranges are within the claimed range. What

the Examiner should focus on is the clear difference, regardless of which particle size within the claimed range, between the granules of mixture (present invention) and the mixture of granules (analogous to Muhammad et al). In each instance, there is an improved dissolution rate for granules of a mixtures of APM and ACE-K (present invention) as compared to mixtures of granules of APM and ACE-K (analogous to Muhammad et al).

Moreover, as explained on page 3 of the specification, the slow dissolution rate of APM is a significant problem in the use of APM for the manufacture of low-calorie soft drinks. An improvement in the dissolution rate of APM provides an improvement in the process of producing such soft drinks. Therefore, the improved dissolution rate for granules of a mixtures of APM and ACE-K (present invention) as compared to mixtures of granules of APM and ACE-K (analogous to Muhammad et al) could not have been expected based on the prior art.


Finally, with respect to point (a) made by the Examiner, it is unclear what the basis for this position is. Applicants note that the data provided in both Declarations fully supports the conclusions drawn. Even assuming an *over-accessed* error as high as 10%, the conclusions drawn from the data are still clearly supported, as there is still an improved dissolution rate for granules of the mixtures of APM and ACE-K (present invention) as compared to mixtures of granules of APM and ACE-K (analogous to Muhammad et al).

For all of these reasons, the rejection is improper and should be withdrawn.

Applicants submit that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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